



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-2986]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

**DATES:** Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-N-2986 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Color Additive Certification--21 CFR Part 80

OMB Control Number 0910-0216--Extension

This information collection helps support FDA regulations governing certification for color additives used in foods, drugs, cosmetics, and medical devices. All color additives must have FDA-approval for their intended use and be listed in the color additive regulations before they are permitted for use in food, drugs, cosmetics, and many medical devices. Some color additives have an additional requirement: they are permitted only if they are from batches that FDA has certified under section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

379e(a)). This means that FDA chemists have analyzed a sample from the batch and have found that it meets the requirements for composition and purity stated in the regulation, called a “listing regulation,” for that color additive. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are established in part 80 (21 CFR part 80). Procedures for color additive certification are set forth in part 80, subpart B (§§ 80.21 through 80.39) and communicate required data elements for requests for certification, limitations of certificates, exemptions from certification for color additive mixtures, treatment of batches pending and after certification, and recordkeeping requirements for respondents to whom a certificate is issued. During the batch certification procedure, a manufacturer of color additives must submit a “request for certification” that provides information about the batch, accompanied by a representative sample of a new batch of color additive, to us. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate that contains a certification lot number for the batch. The batch can then be used in FDA-regulated products marketed in the United States, in compliance with the uses and restrictions in that color additive’s listing regulation. If the sample does not meet the requirements, the batch will be rejected. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

FDA’s web-based color certification information system is available for respondents to request color certification online, track their submissions, and obtain account status information. Prior to submitting a request for certification, the manufacturer must open a color certification account by sending a letter, as an email attachment, signed by responsible company representative, to FDA’s Office of Cosmetics and Colors at [color.cert@fda.hhs.gov](mailto:color.cert@fda.hhs.gov). System

certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates.

We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification. The user fees support FDA's color certification program. Additional information about color additive certification is available at: <https://www.fda.gov/industry/color-additives/color-certification>.

The purpose for collecting this information is to help the Agency assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States.

*Description of Respondents:* The respondents include businesses engaged in the manufacture of color additives used in FDA-regulated foods, drugs, cosmetics, and medical devices. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
80.21 and 80.22; Request for certification accompanied by sample	67	112	7,504	0.22 (13 minutes)	1,651

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
80.39; Record of distribution	67	112	7,504	0.25 (15 minutes)	1,876

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate on our review of the certification requests received over the past 3 years. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Based on a review of the information collection since our last request for OMB approval, we have slightly decreased our burden estimate based on our experience with this program. As a result, although the number of respondents increased, the number of responses per respondent decreased.

**Dated:** August 7, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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